

Application Serial No.: 09/286,530  
Attorney Docket No.: 2C03.1-220  
CIBA Docket No.: CLV-31739/WEJ1239  
PATENT

### **REMARKS/ARGUMENTS**

The Office Action mailed March 15, 2004, Paper No. 30, has been received and reviewed. Claims 1, 2, 4-17, 19-22, 24-40 and 42-55 are pending. Claims 24-39 have been withdrawn from consideration. Claims 1-2, 7-13, 16-17, 40, 42-44, 46-55 have been amended. Claims 56-59 have been added. No new matter has been introduced.

In the specification, two paragraphs has been amended to correct typographical errors.

Claims 1, 9-12, 40, 43, 46, 49 have been amended to indicate the coating and primer features in structural/compositional terms rather than end result or product-by-process terms.

Claims 7, 42-44, 46, 49-55 have been amended to remove unnecessary punctuation or for consistency in punctuation.

The additional amendments are to correspond with the language of the recited amendments.

#### **35 U.S.C. 103**

Claims 1, 2, 4-14, 40, 42, and 44-54 stand rejected under 35 U.S.C. §103(a) as allegedly obvious over U.S. Patent No. 6,158,862 to Patel et al, in view of U.S. Patent No. 5,252,262 to Patel and U.S. Patent No. 5,074,942 to Kearns et al.

Applicants respectfully traverse this ground of rejection.

Patel et al. '862 disclose a multifocal ophthalmic lens having a dye or dyes that block the transmission of near UV and/or blue light to minimize glare or halos. The lens may be made of a suitable material such as polymethylmethacrylate, silicone, soft acrylic, or HEMA. The blue-blocking dye is preferably covalently bonded in the material used to make the lens and will be non-leaching. No other disclosure of the IOL or lens construction is given. The patent contains no reference to haptics or optic nor to one-piece or multi-piece (or similar terms e.g., monolithic or composite).

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Patel '262 discloses a method for attaching a pair of colored haptics to an optic of an intraocular lens containing the steps of providing the peripheral edge of the optic with a pair of holes, inserting the end portions of the colored haptics into the holes, aiming a laser emitting radiation within the visible spectrum at the end portion of the colored haptic within the hole in the optic, and firing the laser so that the radiation passes through the optic essentially without absorption and is absorbed by the colored haptic, thereby causing the haptic to fuse with the optic. The haptic is colored in order to allow the visible spectrum laser energy to pass through the optic but increase the absorption of the laser energy by the haptic. The optic may be made of biocompatible transparent plastic, such as PMMA, polycarbonate and copolymers of esters of acrylic acid and methacrylic acid. Haptics are formed separately from the optic. At least an end portion of the haptic to be attached to the optic must be a colored material. The haptic can have a colored core surround by a clear sheath to minimize possible leaching of the pigment. The haptic may be made of a thermoplastic, such as PMMA, polypropylene, polyimides and polyvinylidene difluoride, and may be either different from or the same material as used in the optic.

Kearns et al. '942 disclose a method for making a monolithic intraocular lens and haptic structure. The invention comprises the process of fabricating an inner core of optically transparent lens material, fabricating segments of an annulus of colored haptic material having the same composition and the same or superior mechanical properties as the lens material, and bonding the inner core and segments into a composite structure that becomes a monolithic rod. The bond is essentially a weld in which the interface is the same material as the lens and haptic. Slices can be cut from the rod to form blanks which can be machined to produce a clear lens with integral colored haptics. The inventors state that a coating can separate from the haptic surface and allow undesirable matter to be loose in the eye. The parts of the composite rod are formed separately. Spacing between the annular segments and between the core and annulus are left for the bonding material. The haptics should not be colored with dyes or colorants which will diffuse. The only material discussed is PMMA.

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Flawed Combination of Patel et al. '862/Patel '262

Patel et al. '862 disclose nothing about the construction of their lens other than the addition of a dye. Since the optic and haptics are not discussed, there is no disclosure whether or not these two portions of an IOL embodiment would be comprised of the same lens material. But even assuming that Patel et al. '862 discloses a monolithic IOL with haptics of the same material as the optic (which is an assumption ONLY), one of skill in the art would not combine Patel et al. '862 with Patel '262. There is no question that Patel '262 is directed to a composite structure, not a monolithic IOL. The dye in the '862 IOL is for blocking blue light whereas the dye in the '262 haptic is for absorbing laser energy to melt the haptic material for bonding to a separate optic. If the '862 IOL is directed to a monolithic structure, one of skill in the art would not be motivated to modify that structure as taught by the '262 disclosure to change to include a dye suitable for absorbing laser energy to bond separate components.

Assuming there is a motivation or suggestion to combine these two references to choose a monolithic structure over a composite structure, the dye of the '262 haptic would be completely unnecessary, and the only dye that one skilled in the art would be motivated to add would be a blue blocking dye. Patel et al. '862 does not disclose whether the blue blocking dye is only added to the optic portion of the lens where it is functional for its purpose or whether it would also be added to the haptic portion of the lens where it would serve no light blocking purpose. Assuming once again, that a combination of the two references would yield a monolithic structure with a dye throughout, one of skill in the art would have no need whatsoever to resort to combining '862 with '262 since under these assumptions '862 would already be a monolithic lens with colored haptics. Thus, there is no motivation AT ALL to combine these two references.

Assuming that one of skill in the art only looks to the portion of '262 discussing a haptic with a colored core surrounded by a clear sheath (rather than '262 read in its entirety), this still does not motivate a combination of the references. The color in a '262 haptic is still for the purpose of bonding, and if no bonding is needed, then no color addition

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would be motivated. The clear sheath of '262 is stated to help minimize leaching of pigment in the colored core of the haptic. However, since Patel et al. '862 teach a non-leaching pigment, one of skill in the art would not be motivated to find a way to minimize leaching of the pigment ('862 teaches away from a pigment that leaches).

ASSUMING instead that '862 would use a leaching pigment, this pigment would have to be AT LEAST in the optic portion of the lens in order to fulfill the pigment's purpose of blocking blue light, in addition to any unnecessary pigment in the '862 haptics. Therefore, looking to this section of '262 for help in leaching would lead one of skill in the art to form a sheath around the WHOLE lens and not just the haptic or any portion thereof since the dye would be found throughout the lens.

Although the '262 haptic can be constructed of polyimide, there is NO teaching in '262 that polyimide prevents or minimizes dye leaching. '262 only teaches that a "clear sheath" addresses dye leaching. There is NO teaching that any of the recited materials prevents or minimizes dye leaching.

The '262 haptic may be constructed of polyimide whether or NOT the core/sheath construction is used for the haptic. The colored core may very well be constructed of polyimide as well as the sheath. There is NO teaching in '262 whether the colored core and clear sheath are made of the same or different materials. If polyimide by itself prevents dye leaching, a clear sheath would not be needed when the colored portion is made of that material. However, '262 does not teach this

'262 also does not teach whether the material of the clear sheath itself minimizes leaching or whether the sheath simply adds additional distance for the dye to diffuse/leach from the core to surrounding tissue. Therefore, one of skill in the art would not assume from this disclosure that any of the disclosed thermoplastic polymers is in fact responsible for the trait of preventing leaching. A conclusion cannot be drawn from this limited disclosure whether any of the disclosed thermoplastics prevent leaching, let alone polyimide.

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Additionally, if the haptic itself (in '262 core/sheath construction, the core) is made of polyimide (in addition to any sheath) and the polyimide inherently promotes fibrosis, the haptic would not be comprised of biologically inert transparent material as required by the current claims.

The examiner never addresses the claim language regarding "unitary structure" or "single casting" found in the present claims. Therefore, the Applicants cannot ascertain whether the examiner is alleging that "monolithic" lenses teach and/or make obvious these limitations. Applicants ask that the examiner address these limitations explicitly.

For these reasons, one of skill in the art would NOT combine the '862 and '262 references as suggested. Further, Patel '262 does NOT teach "it was known to coat haptics ... with polyimide in order to prevent dye or pigment leakage" as asserted by the examiner in his rejection reasoning.

Flawed Addition of Kearns to Patel et al. '862/Patel '262 Flawed Combination

The addition of the Kearns reference to Patel et al. '862, to Patel '262, and/or to the combination thereof, does not rectify the above-recited problems.

Assuming that the '262 reference teaches anything about coatings (assuming sheaths and coatings are the same or obvious), Kearns teaches away from using coatings on a haptic (col. 3, lines 39-42). Kearns teaches that coatings are undesirable due to possible separation from the haptic in the eye. Further, Kearns teaches that the haptics should NOT be colored with dyes or other soluble colorants due to the danger of diffusion but instead should be colored with an insoluble coloring material (col. 6, lines 16-20). The colored haptics of Kearns will be of the same material as the lens (optic). Since Kearns colorants do not leach, there is no motivation found from '262 to add an additional sheath (or coating, as required by the claims) to this haptic material.

Assuming instead that there is some motivation to combine Patel et al. '862 with Kearns (though no such motivation exists) and assuming again that '862 is a monolithic structure and Kearns is a monolithic structure, one of skill in the art would NOT look to the

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composite structure of Patel '262 (especially not to add another dye for laser welding which is not needed for a monolithic structure).

Since the colorants of Patel et al. '862 and Kearns do NOT leach, one of skill in the art is NOT motivated to look for a reference to address leaching. If instead leachable colorants were used, and Patel '262 is looked to only for some teaching regarding colorant leaching (as opposed to '262 as a whole), the only teaching found in Patel '262 is to provide a clear sheath over all colored areas of the IOL (and still does not teach or suggest the composition for the clear sheath). This again would produce a sheath over the WHOLE IOL and not just the haptic or a portion of a haptic.

Clearly these references alone or in combination do not teach a haptic coated with polyimide for any reason. The closest the examiner can come to this limitation with the recited references is a polyimide colored haptic of '262. However, this is not what the claims require.

Prima Facie case of obviousness

In addition to the above discussion regarding the merits of this rejection, the examiner forgets that finding bits and pieces of limitations scattered throughout references does not meet the standard for showing a *prima facie* case of obviousness. The invention must be considered as a whole; the question under 103 is not whether the differences between the references and the claims would have been obvious, but whether the claimed invention as a whole would have been obvious. Additionally, the references must be considered in their entirety.

Claim 1 is

An intraocular lens for surgical implantation in the eye, the lens comprising:

a unitary structure comprising a substantially homogeneous biologically inert transparent material and including an optic portion and a haptic portion, with both the optic and haptic portions comprising a single casting of the same biologically inert transparent

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material and wherein at least a distal portion of the haptic portion comprises a coating of a fibrosis-promoting amount of polyimide.

The examiner has failed to address all claim limitations. The examiner fails to address whether the references alone or in combination teach or make obvious the following limitations

- unitary structure
- single casting of the same ... material
- a distal portion
- fibrosis-promoting amount

It is not clear whether the examiner takes the position that the lens of '862 and/or Kearns meets or makes obvious these limitations. In order to make out a *prima facie* case, the burden is on the examiner to show teaching of suggestion for ALL claim limitations. The examiner has not alleged that these limitations are obvious. The examiner has only addressed a few features which the examiner believes defines the invention and neglects to address all actual limitations found in the claim language.

For the above reasons, the examiner has not made out a *prima facie* case of obviousness for Claim 1. For the same reasons as Claim 1, Claims 2 and 4-14 (which depend from Claim 1) are not obvious in light of the cited references. Further, Claim 40 and the rejected claims depending therefrom (42 and 44-54) are not obvious for the same reasons as Claim 1.

Claims 15-17, 19-22, 43 and 55 stand rejected under 35 U.S.C. §103(a) as allegedly obvious over Patel et al, in view of Kearns et al. and of Patel, as applied, and further in view of U.S. Patent No. 5,047,051 to Cumming.

Applicants respectfully traverse this ground of rejection.

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Cumming '051 does not cure the defects of the rejection combining Patel et al., Kearns, and Patel. Applicants reiterate the defects outlined above and apply them equally to this rejection.

Cumming '051 discloses an intraocular lens having an optic region and an anchor plate attached to the optic region and extending outwardly therefrom at diametrically opposite ends of the optic regions, and a pair of resilient haptic loop members attached to the anchor plate and displaced thereby from the optic region. The invention provides a soft deformable intraocular lens having a rigid haptic anchor plate. The plate provides a base for affixing the haptic loops to the lens and for lens fixation in the capsular bag. Grooves are formed at the end edges of the rigid haptic anchor plate which receive the haptic loops when the IOL is correctly placed in the capsular bag.

The haptics of Cumming are not disclosed to be colored, therefore, under the examiner's reasoning (incorrect reasoning as discussed above), there is no motivation to coat the haptics or a portion thereof.

The grooves in Cumming are for receipt of the haptic loops. If the grooves were coated (or the whole haptics), this could interfere with the receipt of the loops, therefore there would be no motivation to coat these grooves under the examiner's reasoning.

There is no motivation found in the references to modify Cumming from a multi-piece lens to a monolithic lens under the examiner's reasoning. The examiner has provided no suggestion or motivation to modify Patel et al., Kearns, and/or Patel from their structures to the combination plate type + loop haptics. There is no teaching, suggestion or motivation to add a laser-absorbing dye to the Cumming haptics.

In addition to the problems with the merits of this rejection, the Applicants point out the standard for showing a *prima facie* case of obviousness has not been met as discussed above. The invention must be considered as a whole, and the references must be considered in their entirety.



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For these reasons, the examiner has not made out a *prima facie* case of obviousness for Claims 15-17, 19-22, 43, or 55.

Claims 1, 2, 5, 7-14, 20, 22, 40, 42, and 44-53 stand rejected under 35 U.S.C. §103 as allegedly obvious over Kearns in view of Patel.

Applicants respectfully traverse this ground of rejection.

Kearns and Patel '262 are discussed above. The optic and haptic of Kearns are made of PMMA. As noted above, Patel does not teach a coating, nor a coating specifically of PMMA, polyethylene, or polyimide, to prevent leaking of the dye into the eye.

As discussed above, assuming that Patel '262 teaches anything about coatings, Kearns teaches away from using coatings on a haptic (col. 3, lines 39-42). Further, Kearns teaches that the haptics should NOT be colored with dyes or other soluble colorants due to the danger of diffusion but instead with an insoluble coloring material (col. 6, lines 16-20). The colored haptics of Kearns will be of the same material as the lens (optic). Since Kearns colorants do not leach, there is no motivation found from '262 to add an additional sheath/coating to this haptic material.

Assuming one ignored the teaching of Kearns and instead used a soluble/leachable dye, looking to Patel '262 would teach a clear sheath, however, Patel does not teach what this sheath is made of, whether it differs in composition from the colored core, etc. as discussed above.

In addition, the invention must be considered as a whole, and the references must be considered in their entirety.

For the above reasons, the examiner has not made out a *prima facie* case of obviousness for Claim 1. For the same reasons as Claim 1, Claims 2, 5 and 7-14 (which depend from Claim 1) are not obvious in light of the cited references. Claim 20, 22 deal with lenses with plate haptics which are not disclosed or suggested in either reference

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alone or combined. Further, Claim 40 and the rejected claims depending therefrom (42 and 44-53) are not obvious for the same reasons as Claim 1.

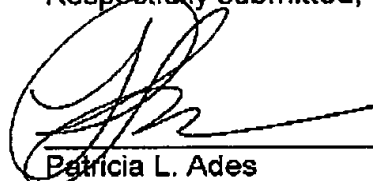
Accordingly, it is respectfully submitted that all grounds of rejection have been overcome.

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### CONCLUSION

In view of the amendments submitted herein and the above comments, it is believed that all grounds of rejection are overcome and that the application has now been placed in full condition for allowance. Accordingly, Applicant earnestly solicits early and favorable action. Should there be any further questions or reservations, the Examiner is urged to telephone Applicant's undersigned attorney at (770) 984-2300.

Respectfully submitted,



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